K121076

510(k) SUMMARY AND EFFECTIVENESS

OCT 9 2012

1. DEVICE NAME:

Generic Name:	System, Image Processing, Radiological
Trade/ Proprietary Name:	Ultrasound Workstation Package, UltraExtend FX
Model Name:	TUW-U001S

2. ESTABLISHMENT REGISTRATION: 2020563

3. CONTACT PERSON AND U.S AGENT INFORMATION:

Contact Person:	Charlemagne Chua Manager, Regulatory Affairs (714) 730-5000
U.S. Agent Name:	Paul Biggins Director, Regulatory Affairs (714) 730-5000
Establishment Name and Address:	Toshiba America Medical Systems, Inc. 2441 Michelle Drive Tustin, CA. 92780

4. MANUFACTURING SITE: Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550
Japan

5. DATE OF SUBMISSION: April 3, 2012 (revised August 3, 2012)

6. DEVICE DESCRIPTION:

UltraExtend FX is a software package that can be installed in a general-purpose personal computer (PC) to enable data acquired from Aplio diagnostic ultrasound system (Aplio 300, Aplio 400 and Aplio 500), to be loaded onto the PC for image processing with other application software product. UltraExtend FX is a post-processing software that implements functionality and operability equivalent to that of the diagnostic ultrasound system, providing a seamless image reading environment from examination using the diagnostic ultrasound system to diagnosis using the PC.

7. INDICATION FOR USE

The UltraExtend FX (TUW-U001S) is designed to allow the use to observe images and perform analysis using the examination data acquired with specified diagnostic ultrasound systems Aplio 300, Aplio 400 and Aplio 500.

8. DESIGN CHANGE

The change allows the ability for the UltraExtend FX Workstation to process images from the Aplio Ultrasound System.

9. SUMMARY OF DESIGN CONTROL ACTIVITIES

PS Risk List for software is attached. Risk Analysis and Design Reviews were conducted. Verification and validations tests were conducted on the subject device through bench testing to confirm device safety and effectiveness. IEC 62304 processes was implemented in the development of the subject device. A declaration of conformity with design controls is included in this submission.

10. TRUTHFUL AND ACCURACY CERTIFICATION

A certification of the truthfulness and accuracy of the UltraExtend FX Workstation described in this submission is provided in this submission.

11. SUBSTANTIAL EQUIVALENCE

UltraExtend (Predicate) is a software that can be installed in a general-purpose personal computer (PC) to enable data acquired using diagnostic ultrasound systems (Aplio Artida SSH-880CV, Aplio XG SSA-790A, or Xario XG SSA-680A) to be loaded onto the PC for various application software programs. This software (UltraExtend) implements functions and operability of the basic measurement, cardiac application measurements using 2D, M and spectral Doppler, and report generation.

UltraExtend FX (Subject) is designed to allow the user to observe images and perform analysis using the examination data acquired from an Aplio diagnostic ultrasound system (Aplio 300, Aplio 400 and Aplio 500). It has the application of basic measurement, cardiac measurement, vaslcular measurement, stress echo, 4D review, Elastography, Auto-IMT and 2D wall motion tracking.

UltraExtend (Model USWS-900A) and UltraExtend FX (Model TUW-U001S) Ultrasound Workstation Package are capable of acquiring images from a specific ultrasound diagnostic systems and perform analysis. Their applications are not the same but the intended use of the software is the same. The UltraExtend FX has been found substantially equivalent to the previously cleared UltraExtend Workstation (Model USWS-900A) and Aplio 500/400/300 Diagnostic Ultrasound System (K110870) referenced in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation, Japan
% Ms. Charlemagne Chua
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

OCT 9 2012

Re: K121076
Trade/Device Name: UltraExtend FX, TUW-U001S, v2.02
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, IYN, and IYL
Dated: September 28, 2012
Received: October 1, 2012

Dear Ms. Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K121076**

Device Name: UltraExtend FX, TUW-U001S, v2.02

Indications for Use:

The UltraExtend FX (TUW-U001S) is designed to allow the user to observe images and perform analysis using the examination data acquired with specified diagnostic ultrasound systems Aplio 500, Aplio 400 and Aplio 300.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

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